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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,038	11/17/2000	Carlos Vonderwalde Freidberg	24079-1071	7272

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EXAMINER	
PREBILIC, PAUL B	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/716,038	FREIDBERG, CARLOS VONDERWALDE	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,29,30,32 and 35-44* is/are pending in the application.

4a) Of the above claim(s) *10,12-20 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,29,30 and 35-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 29, 30, and 35-44, drawn to the stent assembly, classified in class 623, subclass 1.13.

II. Claims 10 and 32, drawn to the method of use, classified in class 623, subclass 1.11.

III. Claims12-20, drawn to the subcombination tissue, classified in class 623, subclass 1.1.

Claim 11 link(s) inventions I and III. The restriction requirement requires the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does

not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require the length, width, and thickness dimensions for patentability. The subcombination has separate utility such as skin graft, to wrap and repair a colon, or for angioplasty without a stent.

Inventions I or III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products could be used in materially different method of use such as in the repair of tubing in a blood oxygenator device or in the repair of a colon.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification or divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

During a telephone conversation with Priscilla Mark on December 4, 2001 a provisional election was made **without** traverse to prosecute the invention of Group I, claims 1-9, 11, 29, 30, and 35-44. **Affirmation of this election must be made by**

applicant in replying to this Office action. Claims 10, 12-20 and 32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The disclosure is objected to because of the following informalities:

The continuing data on page 1 of the specification is not updated with the current status of the parent application. Applicant is respectfully requested to replace the entire paragraph with a clean copy of this paragraph in response to this Office action.

A substitute specification without the claims is required pursuant to 37 CFR 1.125(a) because the top margin of the original specification was too small such that holes were punched through the first line of most pages in order to mount the papers in the file wrapper. For this reason, the first lines of many pages are not clearly legible.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11, 29, 30, 35-38, and 40-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9, 15, 16, 19, and 21-29 of U.S. Patent No. 6,254,627. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to substantially the same invention with the only difference being that the patented claims are more specific and detailed. Since the present claims are read on by the patented claims, it is the Examiner's position that the present claims are clearly obvious in view thereof.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3, 6-9, 11, 29, 35, 38, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Winston et al (US 6,117,166). Winston et al use thinned tissue

over a stent as claimed; see the whole document, especially Figures 1-3, column 1, line 67 to column 2, line 9, column 3, lines 16-59, column 2, lines 48-61, and column 5, lines 4-20.

With regard to claim 9, Applicant is directed to Figure 3.

With regard to claim 38, Applicant is directed to column 5, lines 16-19.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Narciso (WO 94/15583). Narciso anticipates the claim language wherein a cylindrical expandable stent could clearly fit within the biologic tissue or stent of Narciso because stents come in a wide variety of sizes and are expandable from very small diameters; see the whole document, especially pages 8 and 9.

Claim 11 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Turi (US 5,556,414); see Figures 4 and 5 as well as column 2, lines 43-65.

Claims 29, 30, 38, 39, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Love (WO 97/24081). Love anticipates the claim language wherein the tissue is overlapped such that it can unwrap as the stent is expanded; see the whole document, especially pages 8 and 9.

With regard to claim 39, Applicant is directed to page 10, lines 6-8 of Love.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36, 37, and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love (97/24081) in view of Winston et al (US 6,117,166). Love meets the claim language fully except for the thinned state of the tissue as claimed. Winston et al, however teaches that it was known to thin tissue for similar devices; see the abstract and the previously cited portions. Hence, it is the Examiner's position that it would have been obvious to use thinned tissue in the Love device for the same reasons that Winston et al uses the same.

With regard to claim 36 specifically, Love teaches that it was known to have the inner and outer layers longer than the stent but not specifically by less than 5 % as claimed. However, since there is not criticality for this feature, it is the Examiner's position that it would have been prima fascia obvious to match the length of the stent and tissue cover closely in order to reduce the cost of making the device and in order to prevent loose tissue ends from causing thrombosis of the vessel.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al (US 6,117,166) in view of Love (WO 97/24081). Winston et al disclose the use of crosslinked heterograft tissue but not bovine pericardial tissue as claimed. Love, however, teaches that it was known to make similar tissue-stent grafts out of bovine pericardial tissue, venous tissue, or many other types of tissue; Love teaches that such tissues are basically interchangeable. Hence, it is the Examiner's position that it would have been obvious to use bovine pericardial for the tissue of Winston et al because it is less expensive than most tissue and would not pose the problem of disease transmission that porcine or homograft tissue would pose.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al (US 6,117,166) in view of Narciso (WO 94/15583). Winston et al fails to include a therapeutic material in the graft thereof. Narciso teaches that it was known to use therapeutic materials in similar implants. Hence, it is the Examiner's position that it would have been obvious to do the same for the same reasons that Narciso does the same.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738